



ATTORNEY DOCKET NO.: 2004345-0021 (SU-2600 US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ballinger, Marcus Examiner: TBA
Serial No.: 10/726,967 Art Unit: TBA
Filing Date: December 2, 2003
Title: CONSTRUCTS FOR HOMOGENOUSLY PROCESSED
PREPARATION OF BETA SITE APP-CLEAVING ENZYME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (2 pages);
2. Information Disclosure Statement (6 pages);
3. Cited Art (18); and
4. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Nadège M. Lagneau, Ph.D.
Agent for Applicant
Reg. No.: 51,908

Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000

Dated: April 1st, 2004
3675673_1.DOC

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

April 1, 2004 Sandra Saccoccia

Date

Signature

Sandra Saccoccia

Typed or Printed Name of person signing certificate



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STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
☐ A *supplemental* Information Disclosure Statement.

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
<u>April 1, 2004</u>	<u>Sandra Saccoccia</u>
Date	Signature
<u>Sandra Saccoccia</u>	
Typed or Printed Name of person signing certificate	

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☒ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
 - ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise

explanation:

- [] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

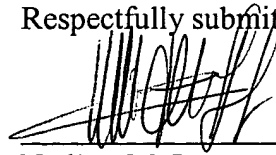
It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

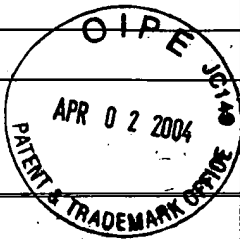
Dated: *April 1st, 2009*

Respectfully submitted,



Nadège M. Lagneau, Ph.D.
Agent for Applicant
Reg. No.: 51,908

CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
(617) 248-5000
(617) 248-4000

FORM PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2004345-0021 (SU-2600 US)		In Re Application No.: 10/726,967	
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				Applicant: Ballinger, Marcus.			
				Filing Date: December 2, 2003			
U.S. PATENT DOCUMENTS							
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass		
	6,545,127	Tang et al.	April 8, 2003	530	350		
	6,440,698	Gurney et al.	August 27, 2002	435	69.1		
	6,420,534	Gurney et al.	July 16, 2002	530	827		
	6,319,689	Powell et al.	November 20, 2001	435	69.1		
U.S. PATENT APPLICATIONS							
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:		
FOREIGN PATENT DOCUMENTS							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
OTHER DOCUMENTS							
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Benjannet, et al., "Post-Translational Processing of b-Secretase (β -Amyloid-Converting Enzyme) and Its Ectodomain Shedding. The Pro- and Transmembrane/Cytosolic Domains Affect its Cellular Activity and Amyloid-Beta Production", <i>J. Biol. Chem.</i> 276 (14): 10879-10887, 2001.						
	Bennett, et al., "A Furin-Like Convertase Mediates Propeptide Cleavage of BACE, The Alzheimer's β -Secretase", <i>J. Biol. Chem.</i> 275 (48): 37712-37717, 2000.						
	Beyer, et al., "Self-Activation of Recombinant Human Lysosomal Procathepsin D at a Newly Engineered Cleavage Junction, 'Short' Pseudocathepsin D", <i>J. Biol. Chem.</i> 271 (26): 15590-15596, 1996.						
	Charlwood, et al., "Characterization of the Glycosylation Profiles of Alzheimer's β -Secretase Protein Asp-2 Expressed in a Variety of Cell Lines", <i>J. Biol. Chem.</i> 276 (20): 16739-16748, 2001.						
	Creemers, et al., "Processing of β -Secretase by Furin and Other Members of the Proprotein Convertase Family", <i>J. Biol. Chem.</i> 276 (6): 4211-4217, 2001.						
	Gruninger-Leitch, et al., "Substrate and Inhibitor Profile of BACE (β -Secretase) and Comparison with Other Mammalian Aspartic Proteases", <i>J. Biol. Chem.</i> 277 (7): 4687-4693, 2002.						

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		Filing Date: December 2, 2003	Group:

	Hong, et al., "Structure of the Protease Domain of Memapsin 2 (β -Secretase) Complexed with Inhibitor", <i>Science</i> , 290 : 150-153, 2000.
	Lin, et al., "Human Aspartic Protease Memapsin 2 Cleaves the β -Secretase Site of B-Amyloid Precursor Protein", <i>Proc. Natl. Acad. Sci. USA</i> , 97 (4): 1456-1460, 2000.
	Mallender, et al., "Characterization of Recombinant, Soluble β -Secretase from an Insect Cell Expression System", <i>Mol. Pharmacol.</i> 59 (3): 619-626, 2001.
	Pinnix, et al., "Convertases Other Than Furin Cleave β -Secretase to its Mature Form". <i>FASEB J.</i> , 15 : 1810-1812, 2001.
	Shi, et al., "The Pro Domain of β -Secretase Does not Confer Strict Zymogen-Like Properties But Does Assist Proper Folding of the Protease Domain", <i>J. Biol. Chem.</i> 276 (13) 10366-10373, 2001.
	Sidera, et al., "Pro-Domain Removal in ASP-2 and the Cleavage of the Amyloid Precursor are Influenced by pH", <i>BMC Biochemistry</i> , 3 : 25-36, 2002.
	Turner, et al., "Subsite Specificity of Memapsin 2 (β -Secretase): Implications for Inhibitor Design", <i>Biochemistry</i> , 40 (34): 10001-10006, 2001.
	Vassar, et al., " β -Secretion Cleavage of Alzheimer's Amyloid Precursor Protein by the Transmembrane Aspartic Protease BACE" <i>Science</i> , 286 : 735-741, 1999.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.